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APPLICATION NO.	F	LING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/519,563	03/06/2000		Markus Haller	P-7354.03 CIP2	8702
27581	7590	12/17/2003		EXAMINER	
MEDTRO	•			THOMPSON, MICHAEL M	
MS-LC340	RONIC PA	RKWAY NE		ART UNIT PAPER NUMBER	
MINNEAPO	DLIS, MN	55432-5604	3763	13	

. DATE MAILED: 12/17/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

	Application No.	Applicant(s)
	09/519,563	HALLER ET AL.
Office Action Summary	Examin r	Art Unit
	Michael M. Thompson	3763
The MAILING DATE of this communication appeariod for Reply	pears on the cover shet with the	correspondenc address
A SHORTENED STATUTORY PERIOD FOR REPL THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1. after SIX (6) MONTHS from the mailing date of this communication.  - If the period for reply specified above is less than thirty (30) days, a rep - If NO period for reply is specified above, the maximum statutory period - Failure to reply within the set or extended period for reply will, by statut - Any reply received by the Office later than three months after the mailin earned patent term adjustment. See 37 CFR 1.704(b).  Status	136(a). In no event, however, may a reply be to ly within the statutory minimum of thirty (30) da will apply and will expire SIX (6) MONTHS from e, cause the application to become ABANDONI	mely filed ys will be considered timely. n the mailing date of this communication. ED (35 U.S.C. § 133).
1) Responsive to communication(s) filed on 04 N	November 2003.	•
2a) ☐ This action is <b>FINAL</b> . 2b) ☑ This	action is non-final.	
3) Since this application is in condition for allowated closed in accordance with the practice under a secondary condition.		
Disposition of Claims		
4) Claim(s) 1-27 is/are pending in the application	<b>).</b>	
4a) Of the above claim(s) is/are withdra	wn from consideration.	
5) Claim(s) is/are allowed.		
6)⊠ Claim(s) <u>1-27</u> is/are rejected.		
7) Claim(s) is/are objected to.		
8) Claim(s) are subject to restriction and/o	or election requirement.	
Application Papers		
9)⊠ The specification is objected to by the Examin		
10) ☐ The drawing(s) filed on is/are: a) ☐ acc		4
Applicant may not request that any objection to the		
Replacement drawing sheet(s) including the correct	•	
11) The oath or declaration is objected to by the E	xaminer. Note the attached Office	e Action of form P1O-152.
Priority under 35 U.S.C. §§ 119 and 120		
a) Acknowledgment is made of a claim for foreigna) All b) Some * c) None of:  1. Certified copies of the priority document 2. Certified copies of the priority documents. Copies of the certified copies of the priority documents. See the attached detailed Office action for a list 13) Acknowledgment is made of a claim for domest since a specific reference was included in the first safety and a claim for domest acknowledgment is made of a claim for domest acknowledgment is made of a claim for domest 14) Acknowledgment is made of a claim for domest 14) Acknowledgment is made of a claim for domest 14) Acknowledgment is made of a claim for domest 15 the first safety and 15 the first safety acctoon of the foreign language priority and 15 the first safety acctoon of the first safety	ts have been received.  Its have been received in Application of the certified copies not received in Application of the certified copies not receive priority under 35 U.S.C. § 119 and the sentence of the specification of the certified copies not receive priority under 35 U.S.C. § 120 covisional application has been restic priority under 35 U.S.C. §§ 120 covisional application has been restic priority under 35 U.S.C. §§ 120 covisional application has been restic priority under 35 U.S.C. §§ 120 covisional application has been restic priority under 35 U.S.C. §§ 120 covisional application has been restic priority under 35 U.S.C. §§ 120 covisional application has been restic priority under 35 U.S.C. §§ 120 covisional application has been restic priority under 35 U.S.C. §§ 120 covisional application has been restic priority under 35 U.S.C. §§ 120 covisional application has been restic priority under 35 U.S.C. §§ 120 covisional application has been restic priority under 35 U.S.C. §§ 120 covisional application has been restic priority under 35 U.S.C. §§ 120 covisional application has been restic priority under 35 U.S.C. §§ 120 covisional application has been restic priority under 35 U.S.C. §§ 120 covisional application has been restic priority under 35 U.S.C. §§ 120 covisional application has been restic priority under 35 U.S.C. §§ 120 covisional application has been restication der 35 U.S.C. §§ 120 covisional application has been restication der 35 U.S.C. §§ 120 covisional application has been restication der 35 U.S.C. §§ 120 covisional application der 35 U.S.C. §§ 120 covisional appli	tion No red in this National Stage  ed. (e) (to a provisional application) or in an Application Data Sheet.  ceived. 0 and/or 121 since a specific
reference was included in the first sentence of t	ne specification or in an Applicati	on Data Sneet. 37 CFR 1.78.
Attachment(s)	_	
1) ⊠ Notice of References Cited (PTO-892) 2) □ Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) ☑ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2	5) Notice of Informal	y (PTO-413) Paper No(s) Patent Application (PTO-152)

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#### **DETAILED ACTION**

#### Election/Restrictions

1. Applicant's election of Figures 2a-b, 4, and 5, claims 1-27 in Paper No. 12 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

## Information Disclosure Statement

- 2. The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A(1) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.
- The information disclosure statement filed 03-06-2000 fails to comply with 37 CFR 1.98(a)(3) because it does not include a concise explanation of the relevance, as it is presently understood by the individual designated in 37 CFR 1.56(c) most knowledgeable about the content of the information, of each patent listed that is not in the English language. It has been placed in the application file, but the information referred to therein has only been considered to the extent of the drawings.

## Specification

4. The disclosure is objected to because of the following informalities: It is the Examiner's position that Applicant has evoked sixth paragraph, means-plus-function language to define

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Applicant's invention. Therefore the Examiner requires the Applicant to amend the specification pursuant to 37 CFR 1.75(d) and MPEP 608.01(o) to explicitly state, with reference to the terms and phrases of the claim element, what structure, materials, and acts perform the function recited in the claim element. Please note that the MPEP clearly states, "Even if the disclosure implicitly sets forth the structure, materials, or acts corresponding to the means-(or step-) plus-function claim element in compliance with 35 U.S.C. 112, first and second paragraphs, the PTO may still require the applicant to amend the specification pursuant to 37 CFR 1.75(d) and MPEP 608.01(o)...". (Also see MPEP 2181 (Rev. 1, Feb.2000))

Appropriate correction is required.

#### Claim Objections

Claims 1-27 are objected to because of the following informalities: It is the Examiner's position that Applicant has evoked sixth paragraph, means-plus-function language to define Applicant's invention. Therefore the Examiner has objected to the claims for the reasons set forth above in the objection to the specification.

Appropriate correction is required.

## Claim Rejections - 35 USC § 112

- 6. The following is a quotation of the second paragraph of 35 U.S.C. 112:
  The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
- 7. Claims 14-25 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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8. Claim 14 recites the limitation "the pumping means" in line 7. There is insufficient antecedent basis for this limitation in the claim. In the claim applicant only refers to one means that may substitute as a pump. The controllable means for pumping appears to constitute a pump, however given applicant's language it is unclear if applicant intends a second pumping means.

# Claim Rejections - 35 USC § 102/103

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.
- 10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
  - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later

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invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

- Claims 1-27 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, 12. under 35 U.S.C. 103(a) as obvious over Tucker (4,221,219) or Cummins (4,340,083) or DeCant, Jr. et al. (4,443,218) or Prosl et al. (4,541,429) or Wojcicki et al. (5,190,522) or Lord et al. (5,328,460) or Slettenmark (5,707,361). Tucker (4,221,219) and Cummins (4,340,083) and DeCant, Jr. et al. (4,443,218) and Prosl et al. (4,541,429) and Wojcicki et al. (5,190,522) and Lord et al. (5,328,460) and Slettenmark (5,707,361) all teach implantable medical devices for infusing comprising all of the limitations of the claims such as sealed means reservoir controlling means with pump and valves acting with piezoelectric elements inherently acting as deflectable electrical means (specifically Prosl et al. and Cummins) having energy storing means such as solenoids etc., wherein the methods are inherently a product of the structure. In the alternative, since it appears that Applicant has provided means plus function language that requires analysis of equivalents pursuant to the standards set forth in the MPEP and partially with respect to Applicant's own disclosure, it is the Examiner's position that any of the structures that Applicant believes are not explicitly recited in the references above have equivalent structures within the references. Since Applicant is one of ordinary skill in the art it is concluded that these equivalent structures will be readily evident upon analysis of each reference.
- Claims 1-27 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Jalink, Jr. et al. (6,071,087) similarly teaches an implantable medical device for infusing comprising all of the limitations of the claims such as sealed means reservoir controlling means with pump and valves acting with piezoelectric

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elements inherently acting as deflectable electrical means having energy storing means wherein the methods are inherently a product of the structure. In the alternative, since it appears that Applicant has provided means plus function language that requires analysis of equivalents pursuant to the standards set forth in the MPEP and partially with respect to Applicant's own disclosure, it is the Examiner's position that any of the structures that Applicant believes are not explicitly recited in the references above have equivalent structures within the references. Since Applicant is one of ordinary skill in the art it is concluded that these equivalent structures will be readily evident upon analysis of each reference.

#### **Double Patenting**

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

15. Claims 1-25 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-30 of U.S. Patent No. 6,048,328. Although the conflicting claims are not identical, they are not patentably distinct from each other because the above mentioned claims recite substantially similar limitations of an implantable medical device for infusing comprising all of the limitations of the claims such as sealed means reservoir

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controlling means with pump and valves acting with piezoelectric elements inherently acting as deflectable electrical means having energy storing means.

Claims 1-27 are rejected under the judicially created doctrine of obviousness-type double 16. patenting as being unpatentable over claims 1-55 of U.S. Patent No. 6,488,652. Although the conflicting claims are not identical, they are not patentably distinct from each other because similarly teaches an implantable medical device for infusing comprising all of the limitations of the claims such as sealed means reservoir controlling means with pump and valves acting with piezoelectric elements inherently acting as deflectable electrical means having energy storing means wherein the methods are further taught almost verbatim.

#### Contacts

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Michael Thompson whose telephone number is (703) 305-1619. The Examiner can normally be reached on Monday through Friday from 9 am to 5 PM.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Primary, Brian Casler, can be reached on (703) 308-3552. The official fax phone number for all submissions to the organization where this application or proceeding is assigned is (703) 872-9306.

Michael M. Thompson

Patent Examiner

ARY EXAMINER

December 12, 2003